



MALAYSIAN RUBBER GLOVE MANUFACTURERS' ASSOCIATION

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Our Ref: MARGMA

40/10/10

Date: 23 October 1999

Your Ref:

Manager
Dockets Management Branch (HFA-305)
FOOD & DRUG ADMINISTRATION
5630 Fishers Lane (Rm. 1061)
ROCKVILLE, MD 20852, U.S.A.

Dear Sir/Madam,

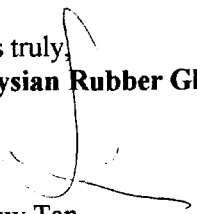
**The Medical Glove Industry ---
Proposed Rule (Federal Register : July 30, 1999,
Volume 64, Number 146)**

We refer to the above matter.

We forward herewith our general views and responses, as per attached, for your kind consideration.

Thank you. With regards,

Yours truly,
Malaysian Rubber Glove Manufacturers' Association


Andrew Tan
Executive Director

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New FDA Regulations: "The Medical Glove Industry"

(Proposed Rule --- Federal Register : July 30, 1999, Volume 64, Number 146)

1. RE-CLASSIFICATION TO CLASS II

- (a) "Class II Medical Devices" is very close to the requirements for Surgical Gloves. The FDA has given valid reasons for special controls.
- (b) As all manufacturers will be in the same level-playing field, Malaysia should be in a better position in terms of capacity and capability of meeting the requirements. MARGMA will not oppose the re-classification issue.
- (c) The Re-Classification will involve a tightening of glove manufacturing standards. Like CE Mark, documentation will be ready for inspection and self-regulation. Long-term manufacturers should find this change to their advantage, as it will weed out weak manufacturers.

2. EXPIRATION DATING

- (a) Most manufacturers do not have real-time stability study of their products, and there is no correlation yet between real-time and accelerated ageing. The absence of specific guidelines/procedures is also noted, e.g. standard test frequency, sampling plan, storage conditions, etc. The FDA should provide standard guidelines/procedures for both real-time and accelerated ageing studies to assist expiry dating of products.
- (b) Manufacturers are urged to commence real-time stability study of their products, in addition to the accelerated ageing practice, and record their data and protocol. However, the industry needs a reasonable time frame for the exercise.
- (c) Current accelerated ageing stability data are based on 7 days at 70°C heat ageing.
- (d) Difficulties may be foreseen for chlorinated gloves, due to heat ageing and real-time storage difference.

3. POWDER

- (a) At present, only the test method (ASTM) for powder-free gloves is available: The test method for powdered gloves is being developed. We purpose that the test methods should first be established and adopted before implementing the requirements.

4. PROTEIN

- (a) The proposed requirement is deemed unacceptable due to glove to glove variations.
- (b) On the expression on weight/content, the Committee advocates for "per gm basis", e.g. $\mu\text{g/g}$ or $\mu\text{g/dm}^2$, moving away from the concept of "per glove" basis.

5. LABELING

- (a) The proposed method is too lengthy, and is deemed unnecessary. The current (1999) ASTM glove specification has already a limit on protein ($200\mu\text{g/dm}^2$) (later powder content as well). It will suffice to quote that the gloves meet the ASTM standards.
- (b) The concept of "recommending" a level is vague; it should be definitive, e.g. required.

Malaysian Rubber Glove Manufacturers' Association

Andrew Tan
Executive Director

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